IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant: Martin J. PAGE et al. Conf.: Unassigned

Appl. No.: NEW Group: Unassigned

Filed: January 28, 2004 Examiner: UNASSIGNED

For: A GLYCOSYLATED ANTIBODY (as amended)

INFORMATION DISCLOSURE STATEMENT (SUBMISSION WITH CONTINUATION-IN-PART OR RULE 1.53(b) CONTINUATION OR DIVISIONAL APPLICATION)

Assistant Commissioner for Patents Washington, DC 20231

January 28, 2004

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicants hereby submit an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-1449 forms, attached hereto.

II. COPIES (check at least one box)

- a. Submitted herewith is a legible copy of (i) each U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. A The only document listed on the PTO-1449 that is enclosed is the Ebert, 1991, Dissertation, University for Soil Cultivation in Vienna, Austria. This reference was newly identified by the Applicants and not previously submitted in the parent application.

c. References Previously Cited or Submitted

Pursuant to 37 C.F.R. § 1.98(d), consideration of information listed on the PTO-1449 forms is requested since any patents, publications, or other information which are listed on the PTO-1449 forms but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

| U.S. Appl. Nos. | <u>U.S. Filing Dates</u> |
|-----------------|--------------------------|
| 10/145,712 | May 16, 2002 |
| 09/642,826 | August 22, 2000 |
| 08/475,607 | June 7, 1995 |
| 08/155,864 | November 23, 1993 |
| 08/046,893 | April 15, 1993 |
| 07/943,143 | September 10, 1992 |
| 07/777,730 | October 16, 1991 |

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

a. DOCUMENTS IN THE ENGLISH LANGUAGE

The attached patents, publications, or other information in the English language do not require a statement of relevancy.

b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

c. X OTHER

The following additional information is provided for the Examiner's consideration.

The undersigned wishes to bring to the Examiner's attention various information that may be relevant to the examination of the above-identified application. It is hoped that this summary of various information will allow the Examiner to conduct a more

meaningful review of the information. Copies of references and Exhibits, to which the Examiner may want to refer, are enclosed with the IDS and are listed on PTO-1449. If the Examiner determines that he would like to review copies of certain Exhibits that are not included with this IDS, he is requested to contact the undersigned and copies will be provided to the Examiner as soon as possible. As the Examiner has been advised, U.S. Patents 5,545,403; 5,545,404 and 5,545,403 of Page are involved in Interference Number 104,532. The '403 and '405 patents are also involved in litigation. A jury verdict in favor of Genentech verdict has been rendered and GlaxoSmithKline is appealing the jury verdict.

Prior Art References and Activities

Various activities occurred prior to the October 16, 1991 U.S. filing date of the present application that the Examiner may determine is relevant to patentability.

UAB Clinical Trials/B72.3 antibodies

In the time period between 1989 and 1991, clinical trials were conducted at the University of Alabama (UAB) by Dr. LoBuglio and others. These clinical trials used a chimeric antibody (B72.3) conjugated to a radionuclide ¹³¹I that specifically bound to the antigen TAG-72 (tumor associated glycoprotein 72). Testimony was presented that the B72.3 antibody may have been expressed in and glycosylated by CHO cells. (LoBuglio Deposition, page 48 line 17 to page 49, line 17 and page 240, line 10 to page 241, line 14.) Additional testimony regarding the B72.3 was presented at the trial in the related district court litigation (Trial Transcript 2770:15-2775:9, 2778:23-2785:1, 2815:16-2819:6, 2821:8-2822:22)

The following references pertain to mAb B72.3 and the trials at University of Alabama:

Baker, et al 1991 Antibody, Immunocongugates, and Radiopharmaceuticals, Vol. 4, No. 4 (1991)

Bodmer, et al 1993 U. S. Patent 5,219,996

Colcher et al. 1989 Cancer Res. 49:1738-1745

Harris et al. 1990 Proc. 34th Oholo Conf, Eilat, Israel pgs. 465-477

Khazaeli et al. 1991 Cancer Res. 51:5461-5466

Khazaeli et al. 1990 HER010300098/315 Abst. Sub. 37th Ann. Mtg of Soc of Nucl. Med.

Khazaeli et al. 1990 HER010300100/317 Abst. Sub. 3rd Conf. On Radioimmunodetect...

Khazaeli et al. 1991 Can. Res. 51:5461-5466

HER010300319 Abst. Sub. 6th Intl. Conf. On Monoclonal Anti.

Khazaeli et al. 1991 Immunoconj.

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Khazaeli et al. 1992 J. of Clin. Immunol. 12(2):116-121
                     HER010300488-517 "Frequent Anti-V Region Immune Resp. to
Khazaeli et al.
                     Mouse..."
LoBuglio &
Saleh
                1992 Am. J. Med. Sci. 304(3):214
LoBuglio et al. 2000 Deposition Transcript from litigation/interference.
LoBuglio et al. 1989 PNAS USA 86:4220-4224
LoBuglio et al. 1990 HER010300318 Abst. Sub. 3<sup>rd</sup> Conf. On Radioimmunodetect...
                     Adv. In Appl. Of Monoclonal Anti. In Clin. Oncl. Chap. 33 pp.
LoBuglio et al. 1991 291-295
LoBuglio et al. 1992 HER010300518 Abst. Sub. ASCO Ann. Mtg, Houston, TX.
               1990 Protocol: UAC 180 NCI:T89-0144 (NCI/CTEP Sheets)
Meredith et al. 1989 Protocol: UAC 180
Meredith et al. 1990 Protocol: UAC 180 (Amended?)
Meredith et al. 1989 Protocol: UAC 079
Meredith et al. 1990 HER010300313 Abst. Sub. 37th Ann. Mtg. For Soc. Of Nuc. Med.
Meredith et al. 1991 HER010300321 Abst. Sub. ASCO Ann. Mtg, Houston, TX.
Meredith et al. 1991 HER010300322 Abst. Sub. 8th Intl. Hammersmith Mtg, Greece
Meredith et al. 1991 HER010300323 Abst. Sub. 38th Ann. Mtg. Soc. Of Nuc. Med.
Meredith et al. 1991 J. Nuc. Med. 32(6):1162-1168
Meredith et al. 1992 Antibod. Immunoconj. & Radiopharm. 5(1):75-80
Meredith et al. 1992 J. Nuc. Med. 33(1):23-29
Meredith et al. 1992 J. Nuc. Med. 9(33):1648-1653
Meredith et al. 1992 J. Nucl. Med. 33:29
Meredith et al. 1995 J. Nuc. Med. 36:2229-2233
                     HER010300320 Abst. Sub. "Comp. localization of murine and
Meredith et al.
                     chimeric B72.3...
                     HER010300324 Abst. Sub. 7th Intl. Conf. On Monoclo. Anti.
Meredith et al.
                     Immunocoj.
                     HER010300434-448 "Effect of Human Immune Resp. on Repeat
Meredith et al.
                     Courses.."
                     HER010300519-544 "Dose Fraction of Radiolabeled Antibodies in
Meredith et al.
                     Patients...."
Meredith et al.
                     Med. Physics "Dosimetry of Solid Tumors"
Meredith et al. 1993
Meredith et al. 1989 Amended Protocol: UAC 180
                     HER010300097/314 Abst. Sub. 5<sup>th</sup> Cong. - WFNM&B, Montreal,
Meredith et al. 1990 Canada
Meredith et al. 1990 HER010300099/316 Abst. Sub. 3<sup>rd</sup> Conf. On Radioimmunodetect...
Primus et al.
               1990 Cancer Immunol. & Immunother. 31:349
Whittle et al. 1987 Protein Eng. 1(6):499-505
               2000 Deposition in Interference 104,532
Yarrenton
                1990 Status Report w/ Master Order Agreement
                1990 Status Report: Phase I Contract - Cancer Therapy
                1991 Status Report Phase I Contract (NO1-CM-97611)
                1992 Status Report Phase I Contract (NO1-CM-97611)
                1994 Status Report: Phase I Contract - Cancer Therapy
                     Phase 1 Contract - CTEP Program (NO1-CM-97611)
                1990 On Study Registration
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It is submitted that the claims of the present application distinguish from the University of Alabama Clinical Trials.

Anti-CD20 antibodies

A number of patents have issued to Robinson et al, including U.S. Patents. 5,500,362, 5,721,108 and 6,120,767. A related PCT publication is WO 87/02671. Applicants will refer to the oldest patent, U.S. Patent 5,500,362, for purposes of discussion. According to the examples of the '362 patent, the recombinant antibody was expressed in Sp2/0 cells (see Col. 18, lines 5-11). Thus, it would seem that Sp2/0 cells would be the preferred cell Other expression hosts are also mentioned, including See Col. 9, lines 53-64 where yeast is indicated as being "one preferred host" (Col. 9, line 53) along with bacterial hosts, such as E. coli, Salmonella typhimurium, Serratia marcescens and various Pseudomonas species (Col. 11, lines 1-8) and mammalian cells PcX63Ag8, Vero cells or CHOK1 (Col. 11, lines The '362 patent contains no description of the actual preparation or characterization of an antibody expressed in CHO Since this patent does not teach the actual preparation cells. of antibodies in CHO cells, and since it does teach the actual production of antibodies in Sp2/0 cells, one skilled in the art would conclude that Sp2/0 cells would be the cell line of choice.

The following references pertain to anti CD-20 antibodies:

Robinson et al. 1996

USP 5500362

Robinson et al. 1998 USP 5721108 Robinson et al. 2000 USP 6120767

Trial Transcript,

2763:17-2767:16,

2792:21-24, 2793:10-14

Anti-CEA Antibodies

Various prior art references teach the preparation of chimeric anti-CEA antibodies. These references will be divided into two groups, the "Shively references" and the "Cabilly references".

Shively References

Various anti-CEA recombinant antibodies are reported in various references in which Shively is either an author or a co-author. Some of these references describe expression of the antibodies in either Sp2/0 cells or CHO cells. However, the data

for antibodies expressed in Sp2/0 cells is more complete and therefore one must assume that Sp2/0 cells are more preferred. In addition, Dr. Shively testified in a Declaration that he contemplated conjugating these antibodies to a radionuclide before using the antibody for therapy (Declaration of Shively of October 30, 2000) and testified in a deposition that he did not contemplate using his antibodies for immunotherapy, but only radioimmunotherapy because "CEA is a poor target antigen for (See, Shively Deposition Transcript of effector function." January 12, 2001 page 56, lines 18-20). These references are discussed in some detail in Cabilly Preliminary Motion 1 and the related Opposition and Reply.

Cabilly References

The Cabilly references include US Patent 4,8176,567, EP 0125023 A1, EP 0125023 B1 and Cabilly et al, PNAS USA 81(11):3273-3277. These references report actual expression of an antibody in E. coli cells. Although CHO cells are mentioned, CHO cells are not singled out as being of particular importance. No actual expression is reported in CHO cells. Therefore, these references are less relevant than the Shively references.

The following references pertain to anti-CEA antibodies:

Cabilly et al. 1989 USP 4816567 Cabilly et al. 1984 EP 0125023 A1 Cabilly et al. 1991 EP 0125023 B1

PNAS USA 81(11):3273-Cabilly et al. 1984 3277 Cabilly & Riggs 1985 Gene 40(1):157-161

Shively 1981

Shively et al. 1992 USP 5081235

Shively 2000

Shively 2001 Declaration of John E. Shively

Deposition Transcript of

Meth. Enzymol. 79:31-48

Shively

Neumaier et al., 1990, Cancer Res. 50:2128-2134. Duda et al., 1990, Surgical Onc. 44:73-77

Campath Antibodies

Prior to October 16, 1991, Campath, an antibody against CDw52, was developed by Medical Research Counsil in Cambridge, United Kingdom. The antibody was engineered and expressed in several different cell lines prior to the humanized IgG1 variant being expressed in Chinese Hamster ovary cells. Predecessors to Campath-1H, other variants of the Campath antibody, were shown to be therapeutic.

The following documents and references pertain to the Campath antibody:

Crowe et al., 1992, Clin. Exp. Immunol. 87:105-110. Cobbold, 1991, Imm. Letters 29:117-122. Cobbold & Waldmann, 1984, Nature 308(5958):460-462 Hale, 1983, Mol. Biol. Med. 1:21-334. Hale, 1990, Progress Report - MRC Wellcome Ther. Antibody Centre Hale et al., 1988, Lancet 2(8625):1394-1399. Finnegan et al., 1997, J. Rheumatol. 24(7):1448-1449 Riechmann et al., 1988, J. Mol. Biol. 203(3):825-828. Riechmann et al., 1988, Nature 332(6162):323-327. Trial Transcript 2758:1-2762:18, 2807:7-2815:15, 2819:7-2821:7

<u>Herceptin</u>

It is Genentech's assertion that certain work was performed with the Herceptin antibody before the earliest U. S. filing date of the Page application (Trial Transcript 1713:5-1724:12, 2788:5-2792:6).

Rituxan

It is Genentech's assertion that in the fall of 1990, IDEC Pharmaceuticals started working on Rituxan and that Phase II clinical trials started in 1994, or late 1993 (Trial Transcript 1786:9-1787:25)

Anti-human placental alkaline phosphatase antibody

DeWaele, et al, Eur. J. Biochem. Vol. 176, 287-295(1988). Trial Transcript 2768:12-2770:14.

Therapeutic proteins (other than recombinant antibodies) expressed by and/or qlycosylated in CHO cells

Prior to the October 16, 1991 filing date, various proteins (other than recombinant antibodies as used in the claims of the present application) were expressed in CHO cells. Some of these proteins were successfully used to treat human patients prior to October 16, 1991. A summary of these proteins follows.

Genentech asserts that in 1983, Genentech was using $E.\ coli$, yeast and cell lines (including CHO) to express various proteins (Trial Transcript, 1687:5-15).

Genentech also asserts that in 1983, Genentech was working with DHFR CHO cell strain to express proteins. It is asserted that this strain was known to produce high levels of proteins (Trial Transcript 1687:25-1688:25).

<u>Tissue Plasminogen Activator (t-PA)</u>

(Trial Transcript 1695: 13-22, 1780:22-1783:4, 2753:2-2757:25)

Recombinant t-PA was expressed in CHO cells, approved by the FDA and used to treat patients in the 1980s. The t-PA was expressed in a CHO K1 derived cell line that was defective in DHFR.

Hepatitis B Vaccine

(Trial Transcript 1698:14-1699:13)

This vaccine, which involved glycoproteins, was in development in 1983-1984 and was expressed in CHO cells.

Factor VIII

(Trial Transcript 1699:14-1701:16)

Factor VIII is a large glycoprotein. It was expressed in CHO cells in the 1983-1984 time frame (Trial Transcript 1700:16-19)

CD4 IqG/Fragments/Hybrid Immunoglobulins

(Trial Transcript 1701:17-1705:10, 1767:4-1779:17, 2785:2-2788:4)

This group of references includes immunoadhesins, and fragments of antibodies. Some of these molecule were expressed in CHO cells in the late 1980s.

Various references were introduced in the interference (Exhibits 1016-1021, which correspond to USPatents 5,116,964, 5,225,538, 5,336,603, 5,428,130, 5,455,165 and 5,514,582, respectively) describe molecules identified as "hybrid immunoglobulins", "heterofunctional immunoadhesons", etc. These molecules are not antibodies. They are fusion proteins that lack antibody binding domains.

| Capon | et | al. | 1992 | USP | 5116964 |
|-------|----|-----|------|-----|---------|
| Capon | et | al. | 1993 | USP | 5225538 |
| Capon | et | al. | 1994 | USP | 5336603 |

| Capon et al. | 1995 | USP 5428130 |
|------------------|------|-------------------------------|
| Capon et al. | 1995 | USP 5455165 |
| Capon et al. | 1996 | USP 5514582 |
| Harris et al | 1990 | J. Biochem. Vol. 194, 611-620 |
| Sekigawa et al. | 1990 | J. Virology 64:5194-5198 |
| Routledge et al. | 1991 | Eur. J. Immunol. 21:2717-2725 |
| USP 5605689 | 1997 | Ammann |

GP120

(Trial Transcript 1705:11-1707:7, 1779:14-1780:20)

Recombinant GP120 (HIV envelope glycoprotein 120) was expressed in CHO cells. The carbohydrate structure of the expressed protein was studied (Mizuochi et al., *Biochem. J.*, 254:599-603 (1988)).

DNAse

(Trial Transcript 1707:8-1708:13)

DNAse is a Genentech product that was developed in the late eighties. It is a recombinant glycoprotein product that was expressed in CHO cells and was used to treat patients with cystic fibrosis.

Other Proteins and Fragments

(Trial Transcript 1708:17-1713:21)

Other proteins or fragments that were expressed in CHO cells are cited in the references listed below.

Dyer et al., 1990, Leukemia & Lymphoma 2:179-193 Stevenson et al., 1991, Blood 77:1071-1079 Peakman et al., 1994, Hum. Antibod. Hybrid. 5:65-74 Routledge et al., 1991, Eur. J. Immunol. 21:2717-2725,

Information Relevant to Inventorship

During the Interference and the District Court litigation,
Genentech questioned whether the designation of inventorship of
the Page patents, the parent to this divisional application, was

proper. The positions of the parties on this issue are set forth in Cabilly Preliminary Motion 5, the Opposition by Glaxo and the Reply by Cabilly. After considering all information relevant to this issue, applicants have determined that the inventorship of the already issued Page patents (USPS 5,545,403, 5,545,404 and 5,545,405) is proper. It is also believed that Drs. Page and Crowe are coinventors of the claims of the present application.

Information Relevant to Enablement

Genentech has questioned the enablement of the claims of the Page patents. The positions of the parties are set forth in Cabilly Preliminary Motion 4, the Opposition by Glaxo and the Reply by Cabilly. It is Glaxo's position that the claims of the Page patents and the claims of the present application fully comply with 35 USC 112. The claims recite the essential features of the invention. The claimed invention has applicability to various types of recombinant antibodies expressed in CHO cells.

III. FEES

This Information Disclosure Statement is being filed concurrent with the filing of a divisional patent application; therefore, no fee is required.

If the Examiner has any questions concerning this IDS or requires a copy of any of the references cited but not provided, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fee required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

Gerald M. Murphy, Jr., #28,977
MaryAnne Armstrong, PhD., #40,069

P.O. Box 747

GMM/MAA/trb 2801-0208P Falls Church, VA 22040-0747 (703) 205-8000

Enclosures:

□ PTO-1449

□ Reference (1 reference only)

☐ Foreign Search Report

☐ Other:

(Rev. 11/02/01)

| orm PTO- | 1449 | | 1. ± | | ATTY DOCKET 2801-0208P | NO. | | APPLICATION NO. NEW-Rule 53(b) Div of 10/145,712 | |
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| INFOR | INFORMATION DISCLOSURE CITATION IN AN APPLICATION | | ATION | APPLICANT Martin J. PAGE et al. | | | | | |
| | | (Use several sheets if necessar | ігу) | | FILING DATE January 28, | 2004 | | GROUP Unassigned | |
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| Examiner Initials | ID | Document Number | Year | 1 | Name | Class | SubClass | Filing Date | |
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| | <u></u> | USP 4399216 | 1983 | Axel et a | ıl. | | | | |
| | | USP 4456748 | 1984 | Goeddel | | | | | |
| | | USP 4816567 | 1989 | Cabilly e | | | | | |
| | | USP 5081235 | 1992 | Shively 6 | | | | | |
| | | USP 5098833 | 1992 | Lasky et | al. | | | | |
| | | USP 5116964 | 1992 | Capon et | al. | | | | |
| | | USP 5225538 | 1993 | Capon et | al. | | | | |
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| | | USP 5428130 | 1995 | Capon et | al. | | | | |
| | | USP 5455165 | 1995 | Capon et | al. | | | | |
| | | USP 5514582 | 1996 | Capon et | al. | | | | |
| | | USP 5460811 | 1995 | Goeddel | et al. | | | | |
| | | USP 5500362 | 1996 | Robinson | n et al. | | | | |
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| | | USP 5721108 | 1998 | Robinson | n et al. | | | | |
| | | USP 5876961 | 1999 | Crowe et | t al. | | | | |
| | | USP 5877293 | 1999 | Adair et | al. | | | | |
| | | USP 5985279 | 1999 | Waldma | nn et al. | | | | |
| - 14 | | USP 6120767 | 2000 | Robinson | n et al. | <u> </u> | | | |
| | | USP 5089397 | 1992 | Kushner | et al. | | | | |
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| | | FILING DATE January 28, 2004 | | GROUP Unassigned | | | | |
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| | EP 0328404 A1 | 1989 | | | | | | |
| | EP 0120694 | 1984 | | | | | | |
| | WO 89/01783 | 1989 | | | | | | |
| | WO 90/10700 | 1990 | | | | | | |
| | WO 91/09967 | 1991 | | | | | | |
| | WO 92/01059 | 1992 | | | | | | |
| | WO 92/07075 | 1992 | | | | | | |
| | WO 93/07899 | 1993 | | | - | | | |
| | WO 93/10817 | 1993 | | | | - | | |
| | EP 0125023 B1 | 1991 | | | - | | | |
| | EP 0338395 A2 | 1989 | | | · · | X | | |
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| | EP 0370581 A1 | 1990 | | | | | | |
| | WO 89/01782 | 1989 | | | | | | |
| | WO 92/16553 | 1992 | | | | | | |
| | WO 92/18629 | 1992 | | | | | | |
| | EP 0338767 A2 | 1989 | | | | | | |
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| Beatty et al., 1989, Cancer Res. 49:1587-1594. |
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| Bindon et al., 1985, Transplant. 40(5):538-544 |
| Bruggemann et al., 1987, J. Exp. Med. 166(5):1351-1361 |
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| Dillman, 1989, Ann. Int. Med. 111:592-600. |
| DiMaggio J. et al., pp.177-203 in Cancer Chemo. & Biol. Resp. Mod. Vol. 11, J. Pinedo et al. (eds.) c. 1990 by Elsevier. |
| De Waele et al., 1988, Eur. J. Biochem. 176:287-295. |
| Duda et al., 1990, J. Surgical Onc. 44:73-77. |
| Dyer et al., 1990, Blood 75:709-714. |
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